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No. 98-1064

In The

Supreme Court of the United States

October Term, 1998

American Academy of Pain Management, a California Non-Profit Corporation, Arnold Fox, M.D., an individual, and B. Eliot Cole, M.D., an individual,

Petitioners,

v.

Ronald Joseph in his official capacity as the Executive Director of the Medical Board of California and not personally.

On Petition For Writ of Certiorari
To the United States Court of Appeals
For the Ninth Circuit

SUPPLEMENTAL REPLY BRIEF

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SUPPLEMENTAL REPLY BRIEF TO THE OPPOSITION TO THE PETITION FOR WRIT OF CERTIORARI

American Academy of Pain Management files this Supplemental Reply Brief because a January 15, 1999 decision of the Court of Appeals for the District of Columbia Circuit creates a conflict between that Court and the Court of Appeals for the Ninth Circuit. This is in addition to the conflicts already existing between the conflicts with the Second, Fifth, Ninth and Eleventh Circuits

This new decision is Pearson v. Shalala of the Court of Appeals for the District of Columbia Circuit. This case emphasizes the necessity of permitting the use of disclaimers where there is "potentially misleading" or allegedly "inherently misleading" advertising which can be made not misleading through additional disclosure. A copy of the case, as made available through Westlaw, is attached in the Supplemental Appendix.

The Court of Appeals requires the alternative of more disclosure in the following words:

> "As best we understand the government, its first argument runs along the following lines: that health claims lacking "significant scientific agreement" are inherently misleading because they have such an awesome impact on consumers as to make it virtually impossible for them to exercise any judgment at the point of sale. It would be as if the consumers were asked to buy something while hypnotized, and therefore they are bound to be misled.

> We think this contention is almost frivolous. See Peel, 496 U.S. at 105, 110 S.Ct. 2281"
> Pearson v. Shalala, Supplemental Appendix, page 10, not officially reported at this time.

The Pearson v. Shalala specifically rejected the Lungren decision which allowed a more deferential and tolerant treatment of statutory and regulatory control of potentially misleading commercial speech.

> "Nor do we agree with the FDA's suggestion (and the Ninth Circuit's holding in Association of Nat'l Advertisers v. Lungren, 44 F.3d 726, 736 (9th Cir.1994)) that the Supreme Court's decision in Fox—a case that did not involve assertedly misleading commercial speech—mandates a more deferential review of government regulations on potentially misleading commercial speech."
> Pearson v. Shalala, Supplemental Appendix, page 15a, not officially reported at this time.

It is these conflicts of the Circuit Courts of Appeals which demonstrates the need to grant the Petition for Writ of Certiorari.

Respectfully submitted,

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Durk PEARSON and Sandy Shaw, American Preventive Medical Association and Citizens for Health, Appellants,

v.

Donna E. SHALALA, Secretary, United States Department of Health and Human Services, et al., Appellees.

No. 98-5043, 98-5084. (Cite as: 1999 WL 12782 (D.C.Cir.))United States Court of Appeals,District of Columbia Circuit. Decided Jan. 15, 1999.

Manufacturers, distributors and consumer organizations brought suit challenging Food and Drug Administration (FDA) regulations that required sellers of dietary supplements to obtain FDA authorization before labeling such supplements with "health claims." The United States District Court for the District of Columbia, 14 F.Supp.2d 10, dismissed action, and plaintiffs appealed. The Court of Appeals, Silberman, Circuit Judge, held that: (1) proposed health claims were not inherently misleading; (2) FDA was required, under commercial speech doctrine, to consider whether inclusion of appropriate disclaimers would negate potentially misleading nature of health claims; and (3) FDA's failure to define phrase "significant scientific agreement" in regulation governing authorization of health claims violated Administrative Procedure Act.

Reversed and remanded with instructions.

Jonathan W. Emord, Burke, VA, argued the cause for appellants. With him on the briefs were James S. Turner, Bellevue, WA, and Betsy E. Lehrfeld.

Christine N. Kohl, Attorney, United States Department

of Justice, argued the cause for appellees. With her on the brief were Frank W. Hunger, Assistant Attorney General, Wilma A. Lewis, United States Attorney, and Douglas N. Letter, Attorney, United States Department of Justice.

Nancy T. Lord-Johnson was on the brief for amici curiae Direct Aids Alternative Information Resources, et al.

David C. Vladeck, Allison M. Zieve, and Bruce Silverglade were on the brief for amici curiae American Cancer Society, et al.

Before: WALD, SILBERMAN, and GARLAND, Circuit Judges.

SILBERMAN, Circuit Judge:

*1 Marketers of dietary supplements must, before including on their labels a claim characterizing the relationship of the supplement to a disease or health-related condition, submit the claim to the Food and Drug Administration for preapproval. The FDA authorizes a claim only if it finds "significant scientific agreement" among experts that the claim is supported by the available evidence. Appellants failed to persuade the FDA to authorize four such claims and sought relief in the district court, where their various constitutional and statutory challenges were rejected. We reverse.

I.

Dietary supplement marketers Durk Pearson and Sandy Shaw, presumably hoping to bolster sales by increasing the allure of their supplements' labels, asked the FDA to authorize four separate health claims. (Pearson and Shaw are supported by two other

appellants, the American Preventive Medical Association, a health care advocacy organization whose members are health care practitioners, and Citizens for Health, a health care advocacy organization whose members are consumers of dietary supplements.) A "health claim" is a "claim made on the label or in labeling of ... a dietary supplement that expressly or by implication ... characterizes the relationship of any substance to a disease or health-related condition." 21 C.F.R. § 101.14(a)(1) (1998). Each of appellants' four claims links the consumption of a particular supplement to the reduction in risk of a particular disease:

(1) "Consumption of antioxidant vitamins may reduce the risk of certain kinds of cancers."

(2) "Consumption of fiber may reduce the risk of colorectal cancer."

(3) "Consumption of omega-3 fatty acids may reduce the risk of coronary heart disease."

(4) ".8 mg of folic acid in a dietary supplement is more effective in reducing the risk of neural tube defects than a lower amount in foods in common form."

Understanding the preapproval requirement for health claims on dietary supplements requires a brief excursus on the broader regulatory framework applicable to dietary supplements, foods, and drugs. A "dietary supplement" is a "product (other than tobacco) intended to supplement the diet" that contains one or more of certain dietary ingredients, including a vitamin, a mineral, an herb or other botanical, or an amino acid, 21 U.S.C.A. § 321(ff)(1)(A)- (D) (Supp.1998) (emphasis added), "is not represented for use as a conventional food or as a sole item of a meal or the diet," id. § 321(ff)(2)(B), and "is labeled as a dietary supplement," id. § 321(ff)(2)(C). A "drug" includes, inter

alia, "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease." 21 U.S.C.A. § 321(g)(1)(B) (Supp.1998). If the product is a "new drug," the product must survive the arduous drug approval process, see 21 U.S.C.A. § 355 (Supp.1998), before the manufacturer may introduce it into interstate commerce, id. § 355(a); see also 21 U.S.C.A. § 343(r)(1)(B) (Supp.1998) (deeming "misbranded" a dietary supplement whose label includes a health claim); 21 U.S.C. § 331 (1994) (prohibiting the introduction of a misbranded product into interstate commerce); 21 U.S.C.A. § 333 (Supp.1998) (prescribing penalties for violations of § 331).

*2 Although there is apparently some definitional overlap between drugs and dietary supplements under the statute, it creates a safe harbor from designation as a "drug" for certain dietary supplements whose labels or labeling [FN1] advertise a beneficial relationship to a disease or health- related condition: If the FDA authorizes a label claim under 21 U.S.C.A. § 343(r), the product is not considered a drug under 21 U.S.C.A. § 321(g)(1). The FDA authorizes a claim only when it determines, based on the totality of publicly available scientific evidence (including evidence from well-designed studies conducted in a manner which is consistent with generally recognized scientific procedures and principles), that there is significant scientific agreement among experts qualified by scientific training and experience to evaluate such claims, that the claim is supported by such evidence. 21 C.F.R. § 101.14(c) (1998). The FDA's authorization comes by an informal rulemaking under the Administrative Procedure Act. See 21 C.F.R. § 101.70 (1998); 5 U.S.C. § 553 (1994). This choice of a

rulemaking rather than an adjudication—which would seem a more natural fit for this individualized determination—was mandated by Congress for the regulation of health claims on food labels, see 21 U.S.C.A. § 343(r)(3)(B)(i), and then adopted by the FDA as well for the regulation of health claims on dietary supplement labels, see id. § 343(5)(D) (authorizing but not specifying regulatory procedure); 21 C.F.R. § 101.70.

The requirement that health claims be approved before being added to the label of a dietary supplement constitutes the primary regulatory hurdle faced by marketers of dietary supplements. The actual sale of dietary supplements is regulated only when the supplement contains a "new dietary ingredient," 21 U.S.C.A. § 350b (Supp.1998), or poses a safety risk, id. § 342(f). See also Food Labeling; General Requirements for Health Claims for Dietary Supplements, 59 Fed.Reg. 395, 396 (1994) (explaining that "the availability of dietary supplements will not be affected by these regulations [of health claims]").

The safe harbor from "drug" status for dietary supplements bearing FDA- approved health claims did not always exist. Prior to 1984, the FDA took the position that a statement that consumption of a food could prevent a particular disease was "tantamount to a claim that the food was a drug ... and therefore that its sale was prohibited until a new drug application had been approved." H.R.REP. NO. 538, 101st Cong., 2d Sess. 9 (1990), reprinted in 1990 U.S.CODE CONG. & ADMIN.NEWS 3336, 3338. But during the mid-1980s, companies began making health claims on foods without seeking new drug approval, a practice that the FDA supported in regulations proposed in 1987. Id. at 3338-39. Congress became concerned that health

claims were increasingly common in the marketplace, and that the FDA had not issued clear, enforceable rules to regulate such claims. Id.

*3 Against this background, and in light of the further concern that the FDA might lack statutory authority to permit health claims on foods without also requiring that the claim meet the premarket approval requirements applicable to drugs, see id., Congress enacted the Nutrition Labeling and Education Act of 1990 (NLEA), Pub.L. No. 101-535, 104 Stat 2353 (codified as amended at 21 U.S.C.A. §§ 301, 321, 337, 343, 371 (1972 & Supp.1998)). The NLEA addressed foods and dietary supplements separately. A health claim on a food may be made without FDA approval as a new drug, or the risk of sanctions for issuing a "misbranded" product, if it has been certified by the FDA as supported by "significant scientific agreement." Id. § 343(r)(3)(B)(i). Congress created a similar safe harbor for health claims on dietary supplements, but delegated to the FDA the task of establishing a "procedure and standard respecting the validity of [the health] claim." Id. § 343(r)(5)(D).

The FDA has since promulgated 21 C.F.R. § 101.14—the "significant scientific agreement" "standard" (quoted above)—and 21 C.F.R. § 101.70—a "procedure" (not particularly relevant to this case)—for evaluating the validity of health claims on dietary supplements. [FN2] In doing so, the agency rejected arguments asserted by commenters—including appellants—that the "significant scientific agreement" standard violates the First Amendment because it precludes the approval of less-well supported claims accompanied by a disclaimer and because it is impermissibly vague. See 59 Fed.Reg. 395, 405, 422-23 (1994). The FDA explained that, in its view, the

disclaimer approach would be ineffective because "there would be a question as to whether consumers would be able to ascertain which claims were preliminary [and accompanied by a disclaimer] and which were not," id. at 405, and concluded that its prophylactic approach is consistent with applicable commercial speech doctrine, see id. at 423 (discussing Central Hudson Gas & Elec. Corp. v. Public Serv. Comm'n, 447 U.S. 557, 563-64, 100 S.Ct. 2343, 65 L.Ed.2d 341 (1980)). The agency, responding to the comment that "significant scientific agreement" is impermissibly vague, asserted that the standard is "based on objective factors" and that its procedures for approving health claims, including the notice and comment procedure, sufficiently circumscribe its discretion.

Then the FDA rejected the four claims supported by appellants. See 21 C.F.R. § 101.71(a) (dietary fiber-cancer), § 101.71(c) (antioxidant vitamins-cancer), § 101.71(e) (omega-3 fatty acids-coronary heart disease) (1998); id. § 101.79(c)(2)(i)(G) (1998) (claim that 0.8 mg of folic acid in a dietary supplement is more effective in reducing the risk of neural tube defects than a lower amount in foods in common form). The problem with these claims, according to the FDA, was not a dearth of supporting evidence; rather, the agency concluded that the evidence was inconclusive for one reason or another and thus failed to give rise to "significant scientific agreement." But the FDA never explained just how it measured "significant" or otherwise defined the phrase. The agency refused to approve the dietary fiber-cancer claim because "a supplement would contain only fiber, and there is no evidence that any specific fiber itself caused the effects that were seen in studies involving fiber-rich

[foods]." 58 Fed.Reg. 53,296, 53,298 (1993) (emphasis added). The FDA gave similar reasons for rejecting the antioxidant vitamins- cancer claim, see id. at 53,302, and the omega-3 fatty acids-coronary heart disease claim, see id. at 53,304. As for the claim that 0.8 mg of folic acid in a dietary supplement is more effective in reducing the risk of neural tube defects than a lower amount in foods in common form, the FDA merely stated that "the scientific literature does not support the superiority of any one source over others." 61 Fed.Reg. 8752, 8760 (1996). The FDA declined to consider appellants' suggested alternative of permitting the claim while requiring a corrective disclaimer such as "The FDA has determined that the evidence supporting this claim is inconclusive." [FN3]

*4 A more general folate-neural tube defect claim supported by appellants— that consumption of folate reduces the risk of neural tube defects—was initially rejected but ultimately approved for both dietary supplement and food labels. See 21 C.F.R. § 101.79 (1998). The parties disagree on what caused the FDA's change of position on this claim. Appellants contend that political objections—Senator Hatch was one of the complainers—concentrated the agency's mind. The FDA insists that its initial denial of the claim was based on a concern that folate consumption might have harmful effects on persons suffering from anemia, and that its concern was alleviated by new scientific studies published after the initial denial of the claim.

Appellants sought relief in the district court, raising APA and other statutory claims as well as a constitutional challenge, but were rebuffed. Pearson v. Shalala, 14 F.Supp.2d 10 (D.D.C.1998). [FN4]

II.

Appellants raise a host of challenges to the agency's action. But the most important are that their First Amendment rights have been impaired and that under the Administrative Procedure Act the FDA was obliged, at some point, to articulate a standard a good deal more concrete than the undefined "significant scientific agreement." Normally we would discuss the non-constitutional argument first, particularly because we believe it has merit. We invert the normal order here to discuss first appellants' most powerful constitutional claim, that the government has violated the First Amendment by declining to employ a less draconian method—the use of disclaimers—to serve the government's interests, because the requested remedy stands apart from appellants' request under the APA that the FDA flesh out its standards. That is to say, even if "significant scientific agreement" were given a more concrete meaning, appellants might be entitled to make health claims that do not meet that standard—with proper disclaimers.

Appellants also claim that the agency's "non-definition" runs afoul of Fifth Amendment concerns for vagueness. This contention is, however, closely connected to appellants' APA challenge and may well not be implicated if appellants' APA challenge affords ultimate relief. Therefore we will defer it until our APA analysis.

A. Disclaimers

It is undisputed that FDA's restrictions on appellants' health claims are evaluated under the commercial speech doctrine. See Bolger v. Youngs Drug Prods. Corp., 463 U.S. 60, 67-68, 103 S.Ct. 2875, 77 L.Ed.2d 469 (1983). It seems also undisputed that the FDA has

unequivocally rejected the notion of requiring disclaimers to cure "misleading" health claims for dietary supplements. (Although the general regulation does not in haec verba preclude authorization of qualified claims, see Melinda Ledden Sidak, Dietary Supplements and Commercial Speech, 48 FOOD & DRUG L.J. 441, 455 (1993), the government implied in its statement of basis and purpose that disclaimers were not adequate, see 59 Fed.Reg. at 405, and did not consider their use in the four sub-regulations before us, see 21 C.F.R. § 101.71(a), (c), (e); id. § 101.79(c)(2)(i)(G).) The government makes two alternative arguments in response to appellants' claim that it is unconstitutional for the government to refuse to entertain a disclaimer requirement for the proposed health claims: first, that health claims lacking "significant scientific agreement" are inherently misleading and thus entirely outside the protection of the First Amendment; and second, that even if the claims are only potentially misleading, under Central Hudson Gas & Elec. Corp. v. Public Serv. Comm'n of New York, 447 U.S. 557, 566, 100 S.Ct. 2343, 65 L.Ed.2d 341 (1980), the government is not obliged to consider requiring disclaimers in lieu of an outright ban on all claims that lack significant scientific agreement.

*5 [1][2][3] If such health claims could be thought inherently misleading, that would be the end of the inquiry.

Truthful advertising related to lawful activities is entitled to the protections of the First Amendment. But when the particular content or method of the advertising suggests that it is inherently misleading or when experience has proved that in fact such advertising is subject to abuse, the States may impose appropriate restrictions. [Inherently m]isleading advertising may be

prohibited entirely. But the States may not place an absolute prohibition on ... potentially misleading information ... if the information also may be presented in a way that is not deceptive.

In re R.M.J., 455 U.S. 191, 203, 102 S.Ct. 929, 71 L.Ed.2d 64 (1982); see also Ibanez v. Florida Dep't of Business and Prof'l Regulation, 512 U.S. 136, 144-46, 114 S.Ct. 2084, 129 L.Ed.2d 118 (1994); Peel v. Attorney Registration and Disciplinary Comm'n of Illinois, 496 U.S. 91, 99-111, 110 S.Ct. 2281, 110 L.Ed.2d 83 (1990). As best we understand the government, its first argument runs along the following lines: that health claims lacking "significant scientific agreement" are inherently misleading because they have such an awesome impact on consumers as to make it virtually impossible for them to exercise any judgment at the point of sale. It would be as if the consumers were asked to buy something while hypnotized, and therefore they are bound to be misled. We think this contention is almost frivolous. See Peel, 496 U.S. at 105, 110 S.Ct. 2281 (rejecting paternalistic assumption that the recipients of a letterhead are "no more discriminating than the audience for children's television"). We reject it. But the government's alternative argument is more substantial. It is asserted that health claims on dietary supplements should be thought at least potentially misleading because the consumer would have difficulty in independently verifying these claims. We are told, in addition, that consumers might actually assume that the government has approved such claims.

[4] Under Central Hudson, we are obliged to evaluate a government scheme to regulate potentially misleading commercial speech by applying a three-part test. First, we ask whether the asserted

government interest is substantial. Central Hudson, 447 U.S. at 566, 100 S.Ct. 2343. The FDA advanced two general concerns: protection of public health and prevention of consumer fraud. The Supreme Court has said "there is no question that [the government's] interest in ensuring the accuracy of commercial information in the marketplace is substantial," Edenfield v. Fane, 507 U.S. 761, 769, 113 S.Ct. 1792, 123 L.Ed.2d 543 (1993), and that government has a substantial interest in "promoting the health, safety, and welfare of its citizens," Rubin v. Coors Brewing Co., 514 U.S. 476, 485, 115 S.Ct. 1585, 131 L.Ed.2d 532 (1995). At this level of generality, therefore, a substantial governmental interest is undeniable.

*6 The more significant questions under Central Hudson are the next two factors: "whether the regulation directly advances the governmental interest asserted," Central Hudson, 447 U.S. at 566, 100 S.Ct. 2343 (emphasis added), and whether the fit between the government's ends and the means chosen to accomplish those ends "is not necessarily perfect, but reasonable," Board of Trustees of the State University of New York v. Fox, 492 U.S. 469, 480, 109 S.Ct. 3028, 106 L.Ed.2d 388 (1989) (discussing Central Hudson, 447 U.S. at 564-66, 100 S.Ct. 2343). [FN5] We think that the government's regulatory approach encounters difficulty with both factors.

It is important to recognize that the government does not assert that appellants' dietary supplements in any fashion threaten consumer's health and safety. [FN6] The government simply asserts its "common sense judgment" that the health of consumers is advanced directly by barring any health claims not approved by the FDA. Because it is not claimed that the product is harmful, the government's underlying—if

unarticulated—premise must be that consumers have a limited amount of either attention or dollars that could be devoted to pursuing health through nutrition, and therefore products that are not indisputably health enhancing should be discouraged as threatening to crowd out more worthy expenditures. We are rather dubious that this simplistic view of human nature or market behavior is sound, but, in any event, it surely cannot be said that this notion—which the government does not even dare openly to set forth—is a direct pursuit of consumer health; it would seem a rather indirect route, to say the least. See Bates v. State Bar of Arizona, 433 U.S. 350, 375, 97 S.Ct. 2691, 53 L.Ed.2d 810 (1977) ("[W]e view as dubious any justification that is based on the benefits of public ignorance."); cf. 44 Liquormart, Inc. v. Rhode Island, 517 U.S. 484, 503, 116 S.Ct. 1495, 134 L.Ed.2d 711 (1996) (opinion of Stevens, J., joined by Kennedy, J., and Ginsburg, J.) ("The First Amendment directs us to be especially skeptical of regulations [of indisputably non-misleading information] that seek to keep people in the dark for what the government perceives to be their own good.").

On the other hand, the government would appear to advance directly its interest in protecting against consumer fraud through its regulatory scheme. If it can be assumed—and we think it can—that some health claims on dietary supplements will mislead consumers, it cannot be denied that requiring FDA pre- approval and setting the standard extremely, perhaps even impossibly, high will surely prevent any confusion among consumers. We also recognize that the government's interest in preventing consumer fraud/confusion may well take on added importance in the context of a product, such as dietary supplements,

that can affect the public's health.

*7 [5] The difficulty with the government's consumer fraud justification comes at the final Central Hudson factor: Is there a "reasonable" fit between the government's goals and the means chosen to advance those goals? Fox, 492 U.S. at 480, 109 S.Ct. 3028. The government insists that it is never obliged to utilize the disclaimer approach, because the commercial speech doctrine does not embody a preference for disclosure over outright suppression. Our understanding of the doctrine is otherwise. In Bates v. State Bar of Arizona, 433 U.S. 350, 97 S.Ct. 2691, 53 L.Ed.2d 810 (1977), the Supreme Court addressed an argument similar to the one the government advances. The State Bar had disciplined several attorneys who advertised their fees for certain legal services in violation of the Bar's rule, and sought to justify the rule on the ground that such advertising is inherently misleading "because advertising by attorneys will highlight irrelevant factors and fail to show the relevant factor of skill." Id. at 372, 97 S.Ct. 2691. The Court observed that the Bar's concern was "not without merit," but refused to credit the notion that "the public is not sophisticated enough to realize the limitations of advertising, and that the public is better kept in ignorance than trusted with correct but incomplete information." Id. at 374-75, 97 S.Ct. 2691. Accordingly, the Court held that the "incomplete" attorney advertising was not inherently misleading and that "the preferred remedy is more disclosure, rather than less." Id. at 376, 97 S.Ct. 2691. In more recent cases, the Court has reaffirmed this principle, repeatedly pointing to disclaimers as constitutionally preferable to outright suppression. See Peel, 496 U.S. at 110, 110 S.Ct. 2281; R.M.J., 455 U.S. at 206 n. 20, 102 S.Ct. 929;

Shapero v. Kentucky Bar Assn., 486 U.S. 466, 478, 108 S.Ct. 1916, 100 L.Ed.2d 475 (1988).

The government suggests that the Supreme Court's guidance on this issue is not so consistent (or coherent?). It points to Friedman v. Rogers, 440 U.S. 1, 99 S.Ct. 887, 59 L.Ed.2d 100 (1979), where the Court, in the course of upholding a ban on the use of trade names by optometrists, stated that "there is no First Amendment rule ... requiring a State to allow deceptive or misleading commercial speech whenever the publication of additional information can clarify or offset the effects of the spurious communication." Id. at 12 n. 1, 99 S.Ct. 887. To be sure, this language cuts against the notion that government must, where possible, regulate misleading commercial speech by requiring disclaimers rather than by imposing an outright ban. But the Court in Friedman made clear the narrowness of its holding as limited to the special status of trade names:

*8 We emphasize ... that the restriction on the use of trade names has only the most incidental effect on the content of the commercial speech of Texas optometrists.... [A] trade name conveys information only because of the associations that grow up over time between the name and a certain level of price and quality of service.... Since the Act does not prohibit or limit the type of informational advertising held to be protected in ... Bates, the factual information associated with trade names may be communicated freely and explicitly to the public.

Id. at 15-16, 99 S.Ct. 887. The government does not assert here that appellants' health claims convey no factual information, only that the factual information conveyed is misleading. Friedman is thus not at odds with the relevant First Amendment principles

established in Bates, which in any event the Supreme Court has reaffirmed—post-Friedman—in R.M.J., Shapero, and Peel.

Nor do we agree with the FDA's suggestion (and the Ninth Circuit's holding in Association of Nat'l Advertisers v. Lungren, 44 F.3d 726, 736 (9th Cir.1994)) that the Supreme Court's decision in Fox—a case that did not involve assertedly misleading commercial speech—mandates a more deferential review of government regulations on potentially misleading commercial speech. In Fox, the Court elaborated on the degree of scrutiny appropriate under the Central Hudson test, making clear that the final step does not require that "the manner of restriction is absolutely the least severe that will achieve the desired end," but only that the fit between the legislature's ends and means is a "reasonable" one. Fox, 492 U.S. at 480, 109 S.Ct. 3028. The Court gave no indication, however, that it was retreating from its holdings in Shapero, R.M.J., and Bates. Rather, the Court described those cases as examples of restrictions that were "substantially excessive, disregarding far less restrictive and more precise means." Fox, 492 U.S. at 479, 109 S.Ct. 3028 (quoting Shapero, 486 U.S. at 476, 108 S.Ct. 1916) (internal quotation marks omitted). It is clear, then, that when government chooses a policy of suppression over disclosure—at least where there is no showing that disclosure would not suffice to cure misleadingness—government disregards a "far less restrictive" means. In any event, we think the Supreme Court's recent decision in 44 Liquormart undermines the Ninth Circuit's holding. The Ninth Circuit relied heavily on Fox's discussion of Posadas de Puerto Rico Assocs. v. Tourism Co. of Puerto Rico, 478 U.S. 328, 106 S.Ct.

2968, 92 L.Ed.2d 266 (1986), for the proposition that a court should not second guess a legislative decision to restrict speech rather than to require more speech. Lungren, 44 F.3d at 736 (citing Fox, 492 U.S. at 479, 109 S.Ct. 3028 (quoting Posadas, 478 U.S. at 344, 106 S.Ct. 2968)). But the Supreme Court expressly disapproved of that aspect of Posadas in 44 Liquormart, 517 U.S. at 509- 10, 116 S.Ct. 1495 (plurality) ("Posadas clearly erred in concluding it was 'up to the legislature' to choose suppression over a less speech-restrictive policy.") (quoting Posadas, 478 U.S. at 344, 106 S.Ct. 2968); 44 Liquormart, 517 U.S. at 531-32, 116 S.Ct. 1495 (O'Connor, J., concurring in the judgment). [FN7]

*9 Our rejection of the government's position that there is no general First Amendment preference for disclosure over suppression, of course, does not determine that any supposed weaknesses in the claims at issue can be remedied by disclaimers and thus does not answer whether the subregulations, 21 C.F.R. § 101.71(a), (c), (e); id. § 101-79(c)(2)(i)(G), are valid. The FDA deemed the first three claims—(1) "Consumption of antioxidant vitamins may reduce the risk of certain kinds of cancers," (2) "Consumption of fiber may reduce the risk of colorectal cancer," and (3) "Consumption of omega-3 fatty acids may reduce the risk of coronary heart disease"—to lack significant scientific agreement because existing research had examined only the relationship between consumption of foods containing these components and the risk of these diseases. The FDA logically determined that the specific effect of the component of the food constituting the dietary supplement could not be determined with certainty. (The FDA has approved similar health claims on foods containing these

components. See, e.g., 21 C.F.R. § 101.79 (folate-neural tube defects).) But certainly this concern could be accommodated, in the first claim for example, by adding a prominent disclaimer to the label along the following lines: "The evidence is inconclusive because existing studies have been performed with foods containing antioxidant vitamins, and the effect of those foods on reducing the risk of cancer may result from other components in those foods." A similar disclaimer would be equally effective for the latter two claims.

The FDA's concern regarding the fourth claim—"0.8 mg of folic acid in a dietary supplement is more effective in reducing the risk of neural tube defects than a lower amount in foods in common form"—is different from its reservations regarding the first three claims; the agency simply concluded that "the scientific literature does not support the superiority of any one source [of folic acid] over others." 61 Fed.Reg. at 8760. But it appears that credible evidence did support this claim, see, e.g., DIET AND HEALTH: IMPLICATIONS FOR REDUCING CHRONIC DISEASE RISK 67 (Committee on Diet and Health, Food and Nutrition Board 1989) (concluding that "[l]osses [of folic acid] in cooking and canning [foods] can be very high due to heat destruction"), and we suspect that a clarifying disclaimer could be added to the effect that "The evidence in support of this claim is inconclusive." Cf. American Home Prods. Corp. v. FTC, 695 F.2d 681, 684, 696-702 (3d Cir.1982) (upholding FTC order requiring advertiser who wished to make an unsubstantiated scientific claim to include a disclaimer that the claim was open to substantial question). [FN8]

The government's general concern that, given the extensiveness of government regulation of the sale of drugs, consumers might assume that a claim on a

supplement's label is approved by the government, suggests an obvious answer: The agency could require the label to state that "The FDA does not approve this claim." Similarly, the government's interest in preventing the use of labels that are true but do not mention adverse effects would seem to be satisfied—at least ordinarily—by inclusion of a prominent disclaimer setting forth those adverse effects.

*10 The government disputes that consumers would be able to comprehend appellants' proposed health claims in conjunction with the disclaimers we have suggested—this mix of information would, in the government's view, create confusion among consumers. But all the government offers in support is the FDA's pronouncement that "consumers would be considerably confused by a multitude of claims with differing degrees of reliability." 59 Fed.Reg. at 405. Although the government may have more leeway in choosing suppression over disclosure as a response to the problem of consumer confusion where the product affects health, it must still meet its burden of justifying a restriction on speech—here the FDA's conclusory assertion falls far short. See Ibanez, 512 U.S. at 146, 114 S.Ct. 2084 ("If the protections afforded commercial speech are to retain their force, we cannot allow rote invocation of the words 'potentially misleading' to supplant the [government's] burden to demonstrate that the harms it recites are real and that its restriction will in fact alleviate them to a material degree.") (citations and internal quotation marks omitted); Edenfield, 507 U.S. at 771, 113 S.Ct. 1792 (invalidating a ban on in-person solicitation by accountants where the government failed to present "studies" or "anecdotal evidence" showing that such solicitation posed dangers of fraud, overreaching, or

compromised independence). [FN9]

We do not presume to draft precise disclaimers for each of appellants' four claims; we leave that task to the agency in the first instance. Nor do we rule out the possibility that where evidence in support of a claim is outweighed by evidence against the claim, the FDA could deem it incurable by a disclaimer and ban it outright. [FN10] For example, if the weight of the evidence were against the hypothetical claim that "Consumption of Vitamin E reduces the risk of Alzheimer's disease," the agency might reasonably determine that adding a disclaimer such as "The FDA has determined that no evidence supports this claim" would not suffice to mitigate the claim's misleadingness. Cf. FTC v. Brown & Williamson Tobacco Corp., 778 F.2d 35, 42-43 (D.C.Cir.1985) (holding, in a false advertising case under the Lanham Act, that a proposed disclaimer would not suffice to cure the misleadingness of an advertising claim). Finally, while we are skeptical that the government could demonstrate with empirical evidence that disclaimers similar to the ones we suggested above would bewilder consumers and fail to correct for deceptiveness, we do not rule out that possibility.

B. The Unarticulated Standard

Wholly apart from the question whether the FDA is obliged to consider appropriate disclaimers is appellants' claim that the agency is obliged to give some content to the phrase "significant scientific agreement." Appellants contend that the agency's failure to do so independently violates their constitutional rights under the First and Fifth Amendments. The First, because producers of dietary supplements are assertedly subject to a "prior restraint" on their protected speech—the labeling of

products. The Fifth, because the agency's approach is so vague as to deprive the producers of liberty (and property?) without due process.

*11 Appellants do not challenge the concept of a prescreening system per se; their complaint is with the FDA's lack of guidance on which health claims will survive the prescreening process. But appellants never connected their vagueness concern with their oblique First Amendment prior restraint argument, and for that reason we need not decide whether prior restraint analysis applies to commercial speech. [FN11] See Carducci v. Regan, 714 F.2d 171, 177 (D.C.Cir.1983). On the other hand, appellants' Fifth Amendment vagueness argument is squarely presented. Still, by prevailing on their APA claim appellants would seem to gain the same relief—invalidation of the FDA's interpretation of the general standard and a remand for more guidance—as they would through a successful Fifth Amendment claim (or indeed a First Amendment prior restraint claim, if it had been properly presented and assuming arguendo that prior restraint analysis applies in the commercial speech context). [FN12]

[6][7] Consideration of this constitutional claim seems unnecessary because we agree with appellants that the APA requires the agency to explain why it rejects their proposed health claims—to do so adequately necessarily implies giving some definitional content to the phrase "significant scientific agreement." We think this proposition is squarely rooted in the prohibition under the APA that an agency not engage in arbitrary and capricious action. See 5 U.S.C. § 706(2)(A) (1994). It simply will not do for a government agency to declare—without explanation—that a proposed course of private action is not approved. See Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co., 463 U.S.

29, 43, 103 S.Ct. 2856, 77 L.Ed.2d 443 (1983) ("[T]he agency must ... articulate a satisfactory explanation for its action...."). To refuse to define the criteria it is applying is equivalent to simply saying no without explanation. Indeed, appellants' suspicions as to the agency's real reason for its volte-face on the general folate-neural tube defect claim highlight the importance of providing a governing rationale for approving or rejecting proposed health claims.

To be sure, Justice Stewart once said, in declining to define obscenity, "I know it when I see it," Jacobellis v. Ohio, 378 U.S. 184, 197, 84 S.Ct. 1676, 12 L.Ed.2d 793 (1964) (Stewart, J., concurring), which is basically the approach the FDA takes to the term "significant scientific agreement." But the Supreme Court is not subject to the Administrative Procedure Act. Nor for that matter is the Congress. That is why we are quite unimpressed with the government's argument that the agency is justified in employing this standard without definition because Congress used the same standard in 21 U.S.C.A. § 343(r)(3)(B)(i). Presumably—we do not decide—the FDA in applying that statutory standard would similarly be obliged under the APA to give it content.

*12 That is not to say that the agency was necessarily required to define the term in its initial general regulation—or indeed that it is obliged to issue a comprehensive definition all at once. But see n.12 supra. The agency is entitled to proceed case by case or, more accurately, sub-regulation by subregulation, but it must be possible for the regulated class to perceive the principles which are guiding agency action. Accordingly, on remand, the FDA must explain what it means by significant scientific agreement or, at minimum, what it does not mean.

* * * *

For the foregoing reasons, we hold invalid the four sub-regulations, 21 C.F.R. § 101.71(a), (c), (e); § 101.79(c)(2)(i)(G), and the FDA's interpretation of its general regulation, id. § 101.14. The decision of the district court is reversed, and the case is remanded to the district court with instructions to remand in turn to the FDA for reconsideration of appellants' health claims.

So ordered.

FN1. "Label" is defined as "a display of written, printed, or graphic matter upon the immediate container of any article." 21 U.S.C. § 321(k) (1994). "Labeling" is defined as "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." Id. § 321(m).

FN2. The FDA uses the same substantive standard and procedure for the regulation of health claims on foods, see 21 C.F.R. § 101.14, 101.70 (1998), even though the substantive standard and procedure for foods, unlike dietary supplements, was prescribed by statute, see 21 U.S.C.A. § 343(r)(3)(B)(i).

FN3. In general, the FDA appears quite reluctant to approve health claims on dietary supplements; only two are currently authorized. See 21 C.F.R. § 101.72(c)(2)(ii)(C) (calcium-osteoporosis); id. § 101.79(c)(2)(ii)(B) (folate-neural tube defects). The FDA has, however, approved several health claims on foods. See, e.g., id. § 101.72(c)(2)(ii) (calcium-osteoporosis); id. § 101.76 (fiber- containing products-cancer); id. § 101.78 (fruits and vegetables- cancer); id. § 101.79 (folate-neural tube defects); id. § 101.81

(soluble fiber-coronary heart disease).

FN4. Two of our sister circuits have been presented with challenges to the general regulation, 21 C.F.R. § 101.14. (Appellants here challenge not only the general regulation but also its application to deny four specific health claims.) The Tenth Circuit held that the challengers did not have standing because their failure to identify a single claim they wish to make, which could be prohibited under the regulations indicated a lack of a concrete, particularized injury. See National Council for Improved Health v. Shalala, 122 F.3d 878, 884-85 (10th Cir.1997). The Second Circuit held that the absence of a specific proposed health claim rendered a challenge to the general regulation unripe for judicial resolution. See Nutritional Health Alliance v. Shalala, 144 F.3d 220, 225-27 (2d Cir.1998), cert. denied, —- U.S. ——, 119 S.Ct. 589, —- L.Ed.2d —— (1998). The Second Circuit did find the challenge to the claim-review procedure as a prior restraint to be ripe for review, holding on the merits that a restraint of up to 540 days was a reasonable and narrowly tailored mechanism by which the FDA could evaluate whether the proposed claims were truthful and non-misleading. See id. at 227-28.

FN5. In Fox, the University had banned sellers of certain products from operating on its property; its principal interest was to promote an educational rather than commercial atmosphere on the campus. Fox, 492 U.S. at 475, 109 S.Ct. 3028. (Unlike our case, there was no contention that the commercial speech was misleading. Id.) The district court found for the University, and the Second Circuit reversed on the ground that the district court had failed to inquire under

the final step of Central Hudson whether the regulation was the "least restrictive measure" that could effectively protect the state's interests, and remanded for further factfinding. Id. at 472-73, 109 S.Ct. 3028. The Supreme Court in turn reversed, explaining that Central Hudson does not impose a "least restrictive means" requirement, but only mandates a "reasonable" fit between means and ends, id. at 480, 109 S.Ct. 3028, and remanded for application of this standard, id. at 486, 109 S.Ct. 3028.

FN6. Drugs, on the other hand, appear to be in an entirely different category—the potential harm presumably is much greater.

FN7. The government is correct to observe that the existence of sufficient alternative channels of communication would count in its favor at the final step of Central Hudson, see Florida Bar v. Went For It, Inc., 515 U.S. 618, 633-34, 115 S.Ct. 2371, 132 L.Ed.2d 541 (1995), but we do not think it is possible to so characterize the situation here. Although a dietary supplement manufacturer remains free to publish articles and books concerning health claims, and may market its dietary supplements with certain physically separate peer-reviewed scientific literature, see 21 U.S.C.A. § 343-2 (Supp.1998), those channels of communication reach consumers less effectively than does a claim made directly on the label because they impose higher search costs on consumers, see John E. Calfee & Janis K. Pappalardo, How Should Health Claims for Foods Be Regulated? 26- 27 (Bureau of Economics, Federal Trade Commission 1989).

FN8. As we noted in Part I supra, there is no indication

that the FDA even considered disclaimers in the context of evaluating these four health claims.

FN9. We recognize that the Supreme Court made these statements in the context of discussing the direct advancement prong of Central Hudson, not the final "reasonable fit" prong. As we noted earlier, we think the government's consumer fraud justification satisfies the direct advancement prong. We rely on Ibanez and Edenfield here because we see no reason why the government's evidentiary burden at the final step of Central Hudson should be any less than at the direct advancement step.

FN10. Similarly, we see no problem with the FDA imposing an outright ban on a claim where evidence in support of the claim is qualitatively weaker than evidence against the claim—for example, where the claim rests on only one or two old studies.

FN11. Compare Nutritional Health Alliance, 144 F.3d at 227-28 (holding that prior restraint analysis applies to commercial speech but that the general health claim regulation, 21 C.F.R. § 101.14, was sufficiently well-defined to survive prior restraint analysis) with Central Hudson, 447 U.S. at 571 n. 13, 100 S.Ct. 2343 (suggesting in dicta that "commercial speech is such a sturdy brand of expression that traditional prior restraint doctrine may not apply to it").

FN12. To be sure, there could be some differences between an APA analysis and a First or Fifth Amendment analysis. It is possible that a standard may be sufficiently well-delineated to satisfy the APA but not the First or Fifth Amendment. And, the APA

may allow the agency to provide guidance in implementation, whereas the First or Fifth Amendment may require the agency to define its standard up front. Neither of these issues is presently before us (they could only conceivably arise after remand to the agency), and we leave them for another day.
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